K012776
1 of 3

NOV 16 2001

510(k)
Summary
Duracon® Constrained PS Tibial Insert

Submission Information

Name and Address of the Sponsor of the 510(k) Submission:

Howmedica Osteonics Corp.
59 Route 17
Allendale, NJ 07401-1677

Contact Person:

Margaret F. Crowe
Regulatory Affairs Consultant
(201) 934-4359

Date of Summary Preparation: August 10, 2001

Device Identification

Proprietary Name: Duracon® Constrained PS Tibial Insert

Common Name: Knee Prosthesis

Classification Name and Reference: Knee Joint, Patellofemorotibial, Polymer/Metal/Polymer, Semi-Constrained, Cemented Prosthesis
21 CFR '888.3560

Predicate Device Identification

The Duracon® Constrained PS Tibial Inserts are substantially equivalent to the Duracon® TS tibial inserts found substantially equivalent in premarket notification K973164.

Device Description

The Duracon® Constrained PS tibial inserts share the same critical design features as the predicate Duracon® TS tibial inserts. Both designs incorporate an intercondylar post

which fits into the intercondylar cavity of the Duracon® TS or PS femoral component. Both designs have a metallic support bracket imbedded into the tibial insert at the time of manufacture. This bracket has two metallic feet which engage the posterior tabs of the baseplate during assembly. The insert-baseplate locking mechanism is augmented by a hex head locking screw in both designs.

Intended Use

The intended use of the Duracon® Constrained PS tibial inserts is identical to that of the predicate Duracon® TS tibial bearing inserts. As with the predicate inserts, the new inserts are single use devices for use as part of a total knee system in primary or revision cemented total knee arthroplasty. These inserts are intended to be used in cases where there is destruction of the joint surfaces with or without bone deformity, where the cruciate ligaments are inadequate, not present, or cannot be preserved during the operative procedure, especially when anterior-posterior stability is impaired due to absence of the patella. The collateral ligaments may or may not be present.

Indications

- Noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis or avascular necrosis,
- Rheumatoid arthritis,
- Correction of functional deformity,
- Revision procedures where other treatments or devices have failed,
- Post-traumatic loss of joint anatomy, particularly when there is patello-femoral erosion, dysfunction or prior patellectomy; and,
- Irreparable fracture of the knee

Contraindications

Absolute contraindications include:

- Overt infection,
- Distant foci of infections (which may cause hematogenous spread to the implant site),
- Rapid disease progression as manifested by joint destruction or bone absorption apparent on roentgenogram,
- Skeletally immature patients
- Cases where there is poor bone stock which would make the procedure unjustifiable,

Conditions presenting an increased risk of failure include:

- Uncooperative patient or patient with neurological disorders who is incapable of following instructions,
- Osteoporosis,
- Metabolic disorders which may impair bone formation,
- Osteomalacia, and
- Previous arthrodesis

Performance Data

Mechanical testing has been performed to demonstrate the substantial equivalence of the subject inserts to the predicate inserts.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 16 2001

Ms. Margaret Crowe
Regulatory Affairs Consultant
Howmedica Osteonics Corporation
59 Route 17
Allendale, New Jersey 07401-1677

Re: K012776
Trade Name: Duracon® Constrained Posterior Stabilized (PS) Tibial Inserts
Regulation Number: 888.3560
Regulation Name: Prothesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer/Metal/Polymer
Regulatory Class: II
Product Code: JWH
Dated: August 17, 2001
Received: August 20, 2001

Dear Ms.Crowe:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K012776

NOV 16 2001

510(k) Number (if known): K

Device Name: Duracon® Constrained PS Tibial Insert

The Duracon® Constrained Posterior Stabilizer (PS) Tibial Inserts are intended to be used with legally marketed Duracon® tibial baseplates and wedges, Duracon® PS and TS femoral components, and patellar components as part of a total knee system in primary or revision cemented total knee arthroplasty. These inserts are intended to be used in cases where there is destruction of the joint surfaces with or without bone deformity, where the cruciate ligaments are inadequate, not present, or cannot be preserved during the operative procedure, especially when anterior-posterior stability is impaired due to absence of the patella. The collateral ligaments may or may not be present. More specific indications/contraindications are listed below:

Indications

- Noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis or avascular necrosis,
- Rheumatoid arthritis,
- Correction of functional deformity,
- Revision procedures where other treatments or devices have failed,
- Post-traumatic loss of joint anatomy, particularly when there is patello-femoral erosion, dysfunction or prior patellectomy; and,
- Irreparable fracture of the knee

for Mark N Milhous

(Division Sign-Off)
Division of Ge[illegible]rative
and Neurologi[illegible] Devices

510(k) Numb[illegible] K012776